

**NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION**

**3781. Adulteration and misbranding of Erbacidin tablets. U. S. v. 493 Vials.**  
(F. D. C. No. 29328. Sample No. 38865-K.)

**LABEL FILED:** May 18, 1950, District of Puerto Rico.

**ALLEGED SHIPMENT:** On or about January 31, 1950, by Carlo Erba, Inc., from New York, N. Y.

**PRODUCT:** 493 vials of *Erbacidin tablets* at San Juan, P. R. Analysis showed that a part of the acetylsalicylic acid in the tablets had undergone decomposition to form salicylic and acetic acids. Some of the tablets contained materially less than the declared amount of acetylsalicylic acid, and some of the tablets were broken and disintegrated.

**LABEL, IN PART:** (Vial) "25 Tablets Erbacidin Each Erbacidin tablet Contains: Pyranisamine maleate \* \* \* Acetylsalicylic acid. . . . . 0.1770 Gm."

**NATURE OF CHARGE:** Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

Adulteration, Section 501 (a) (1), the article consisted in part of a decomposed substance; and, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "Acetylsalicylic acid . . . 0.1770 Gm." Misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of the active ingredient, namely, salicylic acid. The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (e) (2), the label of the article failed to bear the common or usual name of the active ingredient, namely, aspirin. The article was misbranded in this respect when introduced into and while in interstate commerce.

**DISPOSITION:** July 14, 1950. Default decree of condemnation and destruction.

**DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS**

**3782. Misbranding of dextro-amphetamine sulfate tablets, racemic amphetamine sulfate tablets, Seconal Sodium capsules, thyroid tablets, and diethylstilbestrol tablets. U. S. v. Allen Pearman (Pearman's Drug Store). Plea of guilty. Fine of \$750, plus costs. (F. D. C. No. 31306. Sample Nos. 31167-L, 31168-L, 31285-L, 31290-L, 31936-L, 31937-L.)**

**INFORMATION FILED:** February 27, 1952, Eastern District of Illinois, against H. Allen Pearman, trading as Pearman's Drug Store, Paris, Ill.

**ALLEGED SHIPMENT:** On or about May 8 and 9 and June 5, 1951, while a number of *dextro-amphetamine sulfate tablets, racemic amphetamine sulfate tablets, Seconal Sodium capsules, thyroid tablets, and diethylstilbestrol tablets* were being held for sale at Pearman's Drug Store after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

**NATURE OF CHARGE:** Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear a label containing an accurate statement of the quantity of the

contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *racemic amphetamine sulfate tablets* and *Seconal Sodium capsules* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and Section 502 (e) (1), the repackaged *racemic amphetamine sulfate tablets* and *diethylstilbestrol tablets* and a portion of the repackaged *dextro-amphetamine sulfate tablets* failed to bear labels containing the common or usual name of the drugs.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: September 18, 1952. A plea of guilty having been entered, the court imposed a fine of \$750, plus costs.

**3783. Misbranding of Mer-I-Col iron tonic. U. S. v. 58 Bottles \* \* \* (and 4 other seizure actions).** (F. D. C. Nos. 33193, 33210, 33212 to 33214, incl., 33218. Sample Nos. 1649-L, 2393-L, 2394-L, 4684-L, 4686-L, 4688-L, 7711-L.)

**LIBELS FILED:** On or about April 21, 28, and 29, and May 5, 1952, Western District of Pennsylvania, Northern and Middle Districts of Georgia, and Southern District of West Virginia.

**ALLEGED SHIPMENT:** On or about February 8, 11, 22, and 29, and March 6, 24, and 27, 1952, by the National Mer-I-Col Sales Co., from Columbus, Ohio.

**PRODUCT:** 706 8-ounce bottles and 222 16-ounce bottles of *Mer-I-Col iron tonic* at Bradford, Pa., Rome and Columbus, Ga., and Charleston and Huntington, W. Va.

**RESULTS OF INVESTIGATION:** Various representations concerning the conditions for which the product was intended were published in advertisements in local newspapers at the places where the product was located. These advertisements were printed on instructions of, and from mats furnished by, the National Mer-I-Col Sales Co.

**LABEL, IN PART:** (Bottle) "Mer-I-Col Iron Tonic \* \* \* Active Ingredients Iron and Ammonium Citrates, Gentian Root, Thiamine Hydrochloride and a trace of Copper Sulfate (Iron Catalyst) Directions One tablespoonful before each meal, three times a day."

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of rheumatism, arthritis, neuritis, stomach ailments, weak kidneys, rheumatic pains, nervousness, headaches, acids, toxins, bloating, weak back, lumbago, leg pains, lack of vitality and energy, poor appetite, underweight, dizzy spells, indigestion, stomach gas, dyspepsia, intense pain in stomach and chest, wild heart palpitation, fire-like feeling from the throat to the pit of the stomach, loss of weight, tissue, and strength, sour stomach, cramps, spitting up bits of half-digested food and hot, sour liquid, biliousness, sick headaches that last for days, constipation, yellowish complexion, painful, heavy, bloated feeling in the lower stomach, worn-out feeling, sleeplessness, neuralgia, sharp pain over kidneys,